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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

		Application No.	Applicant(s)		
Office Action Summary		10/770,458	OKADA, YOSHIKATSU		
	Office Action Guillinary	Examiner	Art Unit		
		Bradley L. Sisson	1634		
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1)⊠ 2a)⊠ 3)□	Responsive to communication(s) filed on <u>02 Fe</u> This action is FINAL . 2b) This Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro			
Dispositi	on of Claims	•			
5)□ 6)⊠ 7)□ 8)□ Applicati 9)□ 10)□	Claim(s) 1-6 and 8-16 is/are pending in the appear of the above claim(s) 10-14 is/are withdraw Claim(s) is/are allowed. Claim(s) 1-6,8,9,15 and 16 is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or are subject to restriction and/or are specification is objected to by the Examine The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the or Replacement drawing sheet(s) including the correction of the order of declaration is objected to by the Examine The oath or declaration is objected to by the Examine The oath of the oath	r election requirement. r. epted or b) □ objected to by the Edrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).		
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.					
2) 🔲 Notic 3) 🔯 Inforr	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) r. No(s)/Mail Date <u>17 January 2007</u> .	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	nte		

DETAILED ACTION

Election/Restrictions

- 1. Claims 10-14 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

 Applicant timely traversed the restriction (election) requirement in the reply filed on 07 August 2006.
- 2. This application contains claims 10-14 drawn to an invention nonelected with traverse in the reply filed on 07 August 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

3. It is noted that this application appears to claim subject matter disclosed in prior Application No. 10/452,150, filed 03 June 2003. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the

later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

4. If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath

or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required.

Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Specification

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

Claim Rejections - 35 USC § 112

- 6. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 7. Claims 1-9, 15, and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle* & Co. 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in

the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

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- 8. Claims 1-9, 15, and 16 are all drawn to a "probe medium," which is to comprise "a probe capable of specifically binding to a target substance." It is noted that the claims are not limited to any specific nucleotide sequence.
- 9. For purposes of examination, the expression, "a probe," has been interpreted to encompass virtually any polynucleotide sequence, be it comprised of natural or modified nucleotides, and to be directed against virtually any nucleic acid sequence that one wishes to identify, including unknown sequences. Further, the expression has been interpreted as encompassing a plurality of sequences.
- 10. A review of the disclosure finds that only one nucleotide sequence has been disclosed, and that oligomer is but 18 nucleotides in length and is an "artificial" sequence.
- 11. A review of the disclosure fails to find where any useful sequence has been adequately described such that one of skill in the art would readily recognize that applicant had possession of the invention. Further, the specification does not teach how one would recognize those probe and target sequences that are encompassed by the claims from those that are not.

12. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1-9, 15, and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claim Rejections - 35 USC § 101

13. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- 14. Claims 1-9, 15, and 16 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, credible and substantial asserted utility or a well-established utility.
- 15. The claimed "probe medium" is to comprise a probe that is capable of "specifically binding to a target substance." The aspect of a probe being able to bind to a target does not impart utility to the probe unless the target meets the utility requirements. As an example, the claims fairly encompass the use of expressed sequence tags as probes when the target sequence is unknown. The ability of the probe to hybridize to an unknown or uncharacterized target does not impart utility to the probe or to the probe medium in which it is located.
- 16. Claims 1-9, 15, and 16 are also rejected under 35 U.S.C. 112, first paragraph.

 Specifically, since the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

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Response to argument

17. At page 5, bridging to page 6 of the response received 17 January 2007, hereinafter the response, assertions have been made as to what one of skill in the art would understand. This argument has been fully considered and has not been found persuasive. Attention is directed to MPEP 2145.

Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art.

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

See MPEP 2164.06(c).V:

Arguments of counsel may be effective in establishing that an examiner has not properly met his or her burden or has otherwise erred in his or her position. However, it must be emphasized that arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. See In re Budnick, 537 F.2d at 538, 190 USPQ at 424; In re Schulze, 346 F.2d 600, 145 USPQ 716 (CCPA 1965); In re Cole, 326 F.2d 769, 140 USPQ 230 (CCPA 1964).

18. At page 6 of the response applicant's representative asserts that the rejection of claims under 35 USC 101 as lacking a specific, substantial, and credible utility, and the associated rejection under 35 USC 112, first paragraph, as not being enabled, are not understood and are traversed.

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19. As an initial matter, applicant is urged to review the Utility Guidelines (Guidelines),

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which are freely available over the Internet, and can be downloaded from:

http://www.uspto.gov/web/menu/utility.pdf.

20. The present claims more closely parallel Example 9 found in the Guidelines, wherein the application discloses DNA fragments, and claims a sequence, where the sequence is not yet characterized to the point that a "real world" utility exists. In the present case, the claims encompass not only any conceivable DNA (including ESTs), RNA, chimeric or modified nucleotide sequence, but also any other molecule, be it proteinaceous, steroidal, carbohydrate, which can bind to some other molecule. More importantly, the specification has not shown that the genus of "probes," including that of ESTs, has resulted in the identification of useful targets.

- 21. The claims are not limited to those "probes" that bind to known and useful target molecules, but rather, can bind to virtually any molecule. Accordingly, the claimed "probe medium," like the cDNA of Example 9 of the Guidelines, lacks a real world utility, and are appropriately rejected under 35 USC 101 and 112, first paragraph.
- 22. Attention is also directed to *In re Fischer* 76 USPQ2d 1225 (CAFC; September 7, 2005).

Furthermore, Fisher's seven asserted uses are plainly not "specific." Any EST transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses. That is, any EST transcribed from any gene in the maize genome may be a molecular marker or a source for primers. Likewise, any EST transcribed from any gene in the maize genome may be used to measure the level of mRNA in a tissue sample, identify the presence or absence of a polymorphism, isolate promoters, control protein expression, or locate genetic molecules of other plants and organisms. Nothing about Fisher's seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the '643 application or indeed from any EST derived from any organism. Accordingly, we conclude that Fisher has only disclosed general uses for its claimed ESTs, not specific ones that satisfy §101.

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We agree with the Board that the facts here are similar to those in Brenner. There, as noted above, the applicant claimed a process for preparing compounds of unknown use. Similarly, Fisher filed an application claiming five particular ESTs, which are capable of hybridizing with underlying genes of unknown function found in the maize genome. The Brenner court held that the claimed process lacked a utility because it could be used only to produce a compound of unknown use. The Brenner court stated: "We find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product." 383 U.S. at 535. Applying that same logic here, we conclude that the claimed ESTs, which do not correlate to an underlying gene of known function, fail to meet the standard for utility intended by Congress.

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In addition to approving of the Board's reliance on Brenner, we observe that the facts here are even more analogous to those presented in Kirk, 376 F.2d 936, and In re Joly, 376 F.2d 906 [153 USPQ 45] (C.C.P.A. 1967), two cases decided by our predecessor court shortly after Brenner. In Kirk, the applicant sought to patent new steroidal compounds disclosed as having two possible utilities. First, the applicant alleged that the claimed compounds were useful for their "biological activity" because "one skilled in the art would know how to use the compounds ... to take advantage of their presentlyexisting biological activity." Kirk, 376 F.2d at 939. The court rejected this claimed utility on the ground that it was not sufficiently "specific," but was instead "nebulous." Id. at 941.

- 23. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection of claims under 35 USC 101, and under 112, first paragraph, have been maintained, and have also been applied against new claims 15 and 16.
- 24. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

25. Claims 1-9, 15, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 16 is confusing with respect to just what constitutes the metes and bound of "substrate." As presently worded, the "probe" of claim 1 fairly encompasses an enzyme that would act upon a substrate. Also, the claims encompass nucleic acid molecules that have a binding moiety, e.g., biotin, which would be captured by a binding partner, e.g., streptavidin, that could be coated onto a solid support (à.k.a., substrate). Given the breadth of scope of claim 1, and the multiple meanings of "substrate," it is not clear just what constitutes the metes and bound of the claim.

- 27. Claims 1-9, 15, and 16 are confusing as to what constitutes the metes and bound of "a silane coupling agent." Seemingly this term could be construed as any compound that can bind to any silane group, be it directly, indirectly, specifically, and/or non-specifically. In such a case, the term could be construed as encompassing the probe
- 28. In the event that applicant had intended the term to be understood as the substrate for an enzyme, it is less than clear just how claim 16 further limits claim 1, from which it depends.

Double Patenting

- 29. Claims 1-3, 6, 8, 9, and 16 are directed to an invention not patentably distinct from claims 1-5, 20, and 24 of commonly assigned US Patent Application Serial No. 10/452,150.

 Specifically, both sets of claims are directed to a "probe medium," which comprises a probe capable of specifically binding to a target substance, and a silane-coupling agent.
- 30. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300).

 Commonly assigned applications, discussed above, would form the basis for a rejection of the

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noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

- 31. A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.
- 32. Claims 1-3, 6, 8, 9, and 16 of this application conflict with claims 1-5, 20, and 24 of Application No. 10/452,150. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.
- The nonstatutory double patenting rejection is based on a judicially created doctrine 33. grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

- 34. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
- 35. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).
- Claims 1-3, 6, 8, 9, and 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 20, and 24 of copending Application No. 10/452,150. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a "probe medium," which comprises a probe capable of specifically binding to a target substance, and a silane-coupling agent.

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37. This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

38. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 39. Claims 1-3, 6, 8, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/65097 (Hahn et al.).
- 40. Hahn et al., page 16, disclose the use of hydrogel to immobilize biomolecules to a surface of a substrate. At page 39 Hahn et al., disclose the spotting of hydrogel coupled to a biomolecule to a silanated glass slide, whereupon said spotting the droplets polymerize on the surface of a silanated glass slide. The aspect of using hydrogel to couple a biomolecule being coupled to a silane moiety is considered to fairly meet the limitation of "a silane coupling agent" (claim 1) as well as the limitation of "a substance for immobilizing the probe on a substrate."
- The aspect that the probe does bind to the substrate via the hydrogel is considered to meet a limitation of claim 16 in that the probe "has a reaction site for binding to a substrate," which for purposes of examination, has been construed to encompass direct and indirect binding, where said binding can be by covalent, ionic, or electrostatic means.
- 42. At page 19, Hahn et al., disclose that the substrate may be a "biochip," which can comprise glass as well as other materials.

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Hahn et al., page 20, bridging to page 21, disclose using proteins, DNA and RNA as 43. biomolecules in combination with organic solvents that would make the biomolecules to bind to the hydrogel.

Conclusion

- 44. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.
- 45. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
- 46. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.
- 47. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

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48. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

49. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

> Bradley L. Sisson **Primary Examiner**

B. X. Aissor

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